IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
GREENEVILLE DIVISION

NETTIE J. BECKETT and EARL DANIEL BECKETT,	§	
Plaintiffs,	§	CIVIL ACTION NO.: 2:07-cv-00223
	§	Jury Trial Demanded
v.	§	
PFIZER, INC.,	§	
Defendant.	§	

DEFENDANT'S ANSWER

NOW COMES Defendant Pfizer Inc. (improperly captioned in Plaintiff's Complaint as "Pfizer, Inc.") ("Pfizer" or "Defendant") and files this Answer to Plaintiffs' Complaint ("Complaint"), and would respectfully show the Court as follows:

I.
PRELIMINARY STATEMENT

The Complaint does not state in sufficient detail when Plaintiff was prescribed or used Celebrex® (celecoxib) ("Celebrex®"). Accordingly, this Answer can only be drafted generally. Defendant may seek leave to amend this Answer when discovery reveals the specific time periods in which Plaintiff was prescribed and used Celebrex®.

II.
ANSWER

1. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiffs' citizenship and marital status, and, therefore, denies the same. Defendant denies the remaining allegations in this paragraph of the Complaint.

2. Defendant states that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendant admits that Pfizer is a Delaware corporation with its principal place of business in New York. Defendant admits that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States, including Tennessee, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant denies the remaining allegations in this paragraph of the Complaint.

3. Defendant admits that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States, including Tennessee, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant denies the remaining allegations in this paragraph of the Complaint.

4. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's medical condition and whether Plaintiff used Celebrex® and, therefore, denies the same. Defendant denies the remaining allegations in this paragraph of the Complaint.

5. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's medical condition and whether Plaintiff used Celebrex® and, therefore, denies the same. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiffs injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

6. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex® and, therefore, denies the same. Defendant states that, in the ordinary case, Celebrex® was expected to reach users and consumers without substantial change from the time of sale. Defendant denies the remaining allegations in this paragraph of the Complaint.

7. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Celebrex® is unreasonably dangerous, denies that Celebrex® caused Plaintiffs injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

8. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex® and, therefore, denies the same. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant admits that it provided FDA-approved prescribing information regarding Celebrex®. Defendant denies the remaining allegations in this paragraph of the Complaint.

9. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex® and, therefore, denies the same. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with

applicable standards of care and law. Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiffs injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

10. Defendant states that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Celebrex® is defective, and denies the remaining allegations in this paragraph of the Complaint.

11. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex® and, therefore, denies the same. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiffs injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

12. Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiffs injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

13. Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiffs injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

14. Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiffs injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

15. Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiffs injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

Answering the unnumbered paragraph following Paragraph 15 of the Complaint, Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiffs injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

III.
GENERAL DENIAL

Defendant denies all allegations and/or legal conclusions set forth in Plaintiffs' Complaint that have not been previously admitted, denied, or explained.

IV.
AFFIRMATIVE DEFENSES

Defendant reserves the right to rely upon any of the following or additional defenses to claims asserted by Plaintiffs to the extent that such defenses are supported by information developed through discovery or evidence at trial. Defendant affirmatively shows that:

First Defense

1. The Complaint fails to state a claim upon which relief can be granted.

Second Defense

2. Celebrex® is a prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. Defendant's labeling and warning of Celebrex® was at all times in compliance with applicable federal law. Plaintiffs' causes of action against Defendant, therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

Third Defense

3. At all relevant times, Defendant provided proper warnings, information and instructions for the drug in accordance with generally recognized and prevailing standards in existence at the time.

Fourth Defense

4. At all relevant times, Defendant's warnings and instructions with respect to the use of Celebrex® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed and distributed.

Fifth Defense

5. Plaintiffs' action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendant.

Sixth Defense

6. Plaintiffs' action is barred by the statute of repose.

Seventh Defense

7. Plaintiffs' claims against Defendant are barred to the extent Plaintiffs were contributorily negligent, actively negligent or otherwise failed to mitigate their damages, and any recovery by Plaintiffs should be diminished accordingly.

Eighth Defense

8. The proximate cause of the loss complained of by Plaintiffs is not due to any acts or omissions on the part of Defendant. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendant and for whose acts or omissions Defendant is not liable in any way.

Ninth Defense

9. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Defendant cannot be liable.

Tenth Defense

10. Any injuries or expenses incurred by Plaintiffs were not caused by Celebrex®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

Eleventh Defense

11. Defendant affirmatively denies that it violated any duty owed to Plaintiffs.

Twelfth Defense

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a "learned intermediary" in determining the use of the product. Celebrex® is a prescription medical product, available only on the order of a licensed physician. Celebrex® provided an adequate warning to Plaintiff's treating and prescribing physicians.

Thirteenth Defense

13. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

Fourteenth Defense

14. Celebrex® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Celebrex® at the time of the occurrence of the injuries alleged by Plaintiffs were legally adequate for its approved usages.

Fifteenth Defense

15. Plaintiffs' causes of action are barred in whole or in part by the lack of a defect as the Celebrex® allegedly ingested by Plaintiff was prepared in accordance with the applicable standard of care.

Sixteenth Defense

16. Plaintiffs' alleged injuries/damages, if any, were the result of misuse or abnormal use of the product Celebrex® after the product left the control of Defendant and any liability of Defendant is therefore barred.

Seventeenth Defense

17. Plaintiffs' alleged damages were not caused by any failure to warn on the part of Defendant.

Eighteenth Defense

18. Plaintiffs' alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Celebrex®.

Nineteenth Defense

19. Plaintiffs knew or should have known of any risk associated with Celebrex®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

Twentieth Defense

20. Plaintiffs are barred from recovering against Defendant because Plaintiffs' claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

Twenty-first Defense

21. Plaintiffs' claims are barred in whole or in part under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

Twenty-second Defense

22. The manufacture, distribution and sale of the pharmaceutical product referred to in Plaintiffs' Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiffs' causes of action are preempted.

Twenty-third Defense

23. Plaintiffs' claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

Twenty-fourth Defense

24. Plaintiffs' claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

Twenty-fifth Defense

25. Plaintiffs' claims are barred in whole or in part because Defendant provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

Twenty-sixth Defense

26. Plaintiffs' claims are barred or limited to a product liability failure to warn claim because Celebrex® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

Twenty-seventh Defense

27. Plaintiffs' claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

Twenty-eighth Defense

28. Plaintiffs' claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

Twenty-ninth Defense

29. To the extent that Plaintiffs are seeking punitive damages, Plaintiffs have failed to plead facts sufficient under the law to justify an award of punitive damages.

Thirtieth Defense

30. Defendant affirmatively avers that the imposition of punitive damages in this case would violate Defendant's rights to procedural due process under both the Fourteenth Amendment of the United States Constitution and the Constitution of the State of Tennessee, and would additionally violate Defendant's rights to substantive due process under the Fourteenth Amendment of the United States Constitution.

Thirty-first Defense

31. Plaintiffs' claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution.

Thirty-second Defense

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

Thirty-third Defense

33. Plaintiffs' punitive damage claims are preempted by federal law.

Thirty-fourth Defense

34. In the event that reliance was placed upon Defendant's nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendant.

Thirty-fifth Defense

35. Plaintiffs failed to provide Defendant with timely notice of any alleged nonconformance to any express representation.

Thirty-sixth Defense

36. To the extent that Plaintiffs' claims are based on a theory providing for liability without proof of causation, the claims violate Defendant's rights under the United States Constitution.

Thirty-seventh Defense

37. Plaintiffs' claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical product were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

Thirty-eighth Defense

38. To the extent that Plaintiffs seek punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution, and

applicable provisions of the Constitution of the State of Tennessee. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiffs; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiffs and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendant; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1, 111 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

Thirty-ninth Defense

39. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Celebrex®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

Fortieth Defense

40. The claims asserted in the Complaint are barred because Celebrex® was designed, tested, manufactured and labeled in accordance with the state-of-the-art industry standards existing at the time of the sale.

Forty-first Defense

41. If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Defendant and over whom Defendant had no control and for whom Defendant may not be held accountable.

Forty-second Defense

42. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

Forty-third Defense

43. Plaintiffs' claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

Forty-fourth Defense

44. Plaintiffs' claims are barred because Plaintiffs' injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiffs, and were independent of or far removed from Defendant's conduct.

Forty-fifth Defense

45. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® did not proximately cause injuries or damages to Plaintiffs.

Forty-sixth Defense

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiffs did not incur any ascertainable loss as a result of Defendant's conduct.

Forty-seventh Defense

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

Forty-eighth Defense

48. The claims must be dismissed because Plaintiff would have taken Celebrex® even if the product labeling contained the information that Plaintiffs contend should have been provided.

Forty-ninth Defense

49. The claims asserted in the Complaint are barred because the utility of Celebrex® outweighed its risks.

Fiftieth Defense

50. Plaintiffs' damages, if any, are barred or limited by the payments received from collateral sources.

Fifty-first Defense

51. Defendant's liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiffs' alleged damages, if any, are determined. Defendant seeks an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiffs.

Fifty-second Defense

52. Plaintiffs' claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

Fifty-third Defense

53. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq*., and regulations promulgated there under, and Plaintiffs' claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Celebrex®. Accordingly, Plaintiffs' claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

Fifty-fourth Defense

54. Plaintiffs' misrepresentation allegations are not stated with the degree of particularity required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

Fifty-fifth Defense

55. In *Hill v. City of Germantown*, 31 S.W. 3d 234, (Tenn. Sup. Ct. 2000), the Tennessee Supreme Court held that, "loss of consortium damages in a wrongful death claim are wholly contained within the award for wrongful death." Accordingly, no distinct cause of action for loss of consortium exists under the Tennessee wrongful death statute, T.C.A. § 20-5-113. Plaintiffs' claims seeking damages for loss of consortium should be dismissed.

Fifty-sixth Defense

56. Defendant affirmatively avers that the product at issue complied with all government standards as referred to in T.C.A. § 29-28-104 and said product was not then at the time of manufacture and sale and is not now in an unreasonably dangerous condition in regard to matters covered by these standards and Defendant pleads the Tennessee Products Liability Act of 1978, T.C.A. § 29-28-101, *et seq.*, in full bar of any liability on the part of Defendants.

Fifty-seventh Defense

57. Defendant affirmatively avers that Plaintiff's action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, T.C.A. Section 28-3-104, and same is plead in full bar of any liability as to Defendant.

Fifty-eighth Defense

58. Defendant reserves the right to supplement its assertion of defenses as it continues with its factual investigation of Plaintiffs' claims.

V.
JURY DEMAND

Defendant hereby demands a trial by jury.

VI.
PRAYER

WHEREFORE, Defendant prays for judgment as follows:

1. That Plaintiffs take nothing from Defendant by reason of the Complaint;
2. That the Complaint be dismissed;
3. That Defendant be awarded its costs for this lawsuit;
4. That the trier of fact determine what percentage of the combined fault or other liability of all persons whose fault or other liability proximately caused Plaintiffs' alleged injuries, losses or damages is attributable to each person;
5. That any judgment for damages against Defendant in favor of Plaintiffs be no greater than an amount which equals its proportionate share, if any, of the total fault or other liability which proximately caused Plaintiffs' injuries and damages; and

6. That Defendant have such other and further relief as the Court deems appropriate.

Respectfully submitted,

/s/ Jennifer Kiesewetter .
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ATTORNEYS FOR DEFENDANT PFIZER INC.

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing document was served upon George Todd East, 155 Shelby Street, Kingsport, Tennessee 37660, via CM/ECF this 12th day of September, 2007.

/s/ Jennifer Kiesewetter .
Jennifer Kiesewetter